UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/985,007	12/04/97	MIURA N	2550/KIP

HM12/0426

ROSENMAN & COLIN LLP
575 MADISON AVENUE
NEW YORK NY 10022-2585

EXAMINER	
CHIN,C	
ART UNIT	**PAPER NUMBER**
1641	23

DATE MAILED: 04/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 23

Application Number: 08/985,007
Filing Date: 12/04/97
Appellant(s): Miura et al

Date mailed 4/26/01

Shahan Islam
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 1/3/01.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 14-27 stand or fall together because while appellant's brief does include a statement that this grouping of claims does not stand or fall together, appellants failed to provide any reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,844,613	Batchelder et al	7-1989
4,997,278	Finlan et al	3-1991
5,229,833	Stewart	7-1993
5,047,213	Finlan et al	9-1991

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 112

1. Claims 14-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a.) Claim 14 is vague and confusing. The last line of the claim is not clear as to whether the antigen fixed to the resonance material is the "medical substance" or a reagent for detection of the "medical substance". If the antigen is the "medical substance", then the claimed apparatus is

essentially a "used apparatus" because the "medical substance" is already present on the resonance material and thus cannot be used to assay a sample to determine the amount of medical substance in the sample as set forth in the preamble of the claim. If the antigen is the "medical substance", then a corresponding antibody specific for the antigen would have to be present on the resonance material to permit detection of the antigen. If the antigen is a reagent for detection of a medical substance, then the claim should be amended to state that the antigen is specific for the medical substance.

In response to this rejection Appellants argue that claim 14 clearly defines that the antigen fixed to the resonance material is a medical substance and not a reagent for detection of the medical substance. Furthermore, the claimed invention does not utilize conventional detecting technology, i.e. the use of an antibody for detection of antigen as asserted by the Examiner.

Appellant's arguments have been considered but are not convincing. While it is true that the claims must be read in light of the specification, the claims must clearly set forth the claimed invention. The phrase in question in the last line of the claim, as set forth in the above rejection, is not clear as to the nature and function of the "medical substance". If the "medical substance" is indeed an antigen as argued by Appellants then the preamble of the claim should read --An apparatus for measuring an antigen-- to clearly define the function of the claimed apparatus for measuring an antigen which appears to be what Appellants are trying to say in the last line of claim 14 but the antigen should not be fixed to the apparatus since the antigen is what is to be detected. As pointed out in the rejection, the last line of claim 14 suggests that the antigen is a

reagent for detection of the "medical substance" since the claim requires the antigen to be fixed to the resonance material and thus would be considered a component of the apparatus instead of what is to be detected by the apparatus.

While the claimed apparatus may not utilize conventional detecting technology as argued by Appellants, the language of claim 14 does not exclude the use of antibodies as in conventional detecting technology for the detection of antigens. The open "comprising" language does not exclude the use of antibodies on the resonance material as a reagent for the detection of antigens.

(b.) Claims 20 and 23 are further vague and confusing as it is not clear as to how the antigen can be fixed to a surface of the metal film which is opposite to the surface prism when the metal film is formed on the surface of the prism. The claim fails to recite the presence of another metal film that is positioned opposite the metal film on the surface of the prism to support the antigen.

This rejection is withdrawn because Appellant's argument is convincing to setting forth the position of the antigen relative to the metal film.

(c.) Claim 22 suffers from the same deficiency as claim 14.

(d.) Claim 24 is vague and confusing. In lines 4-5, is the antigen the "medical substance" or a reagent for detection of the "medical substance"? If the antigen is the "medical substance", then a corresponding antibody specific for the antigen would have to be present on the resonance material to permit detection of the antigen. Lines 6-7 are confusing as it appears to recite that the antibody is coupled to the "medical substance" and to the sample? Furthermore, is the antibody

specific for the antigen or the "medical substance"? Lines 8-9 are confusing the recitation of "the mixture" lacks antecedent support and are redundant as it appears that sample and antibody were already contacted with the resonance material in lines 4-7. Lines 11-12 are vague because any change in the properties of the incident light is the result of "medical substance" and/or antibodies being bound to the resonance material which is not clearly set forth in the detection step recited in these two lines.

In response to this rejection, Appellants argue that lines 4-5 of claim 24 define the "medical substance" as an antigen and not a reagent for detection of the medical substance. Appellants argue that lines 6-7 clearly set forth that the antibody is coupled with the medical substance and is specific for the medical substance which is the antigen. Appellants argue that the mixture in lines 8-9 means the mixture of antibody and sample defined in lines 6-7. Appellants also argue that lines 11-12 are clear as to what causes the change in incident light or reflected light.

Appellant's arguments have been considered but are not convincing. Contrary to Appellant's argument, lines 4-5 do not define the "medical substance" as an antigen. Lines 4-5 do not set forth any clear relationship between the "medical substance" and antigen. The claim recites "fixing a medical substance to [redacted] be measured to a resonance material" but does not say the antigen is the medical substance. There is no language in lines 4-5 that defines the medical substance as being an antigen. Line 5 appears to relate the antigen to the resonance phenomenon and not the medical substance.

With respect to lines 6-7, these lines are clear that the antibody is coupled to the medical substance; however, the last part of line 7 (i.e. "...to said sample") suggests that the antibody is also coupled to the sample.

With respect to the recitation of "the mixture" in lines 8-9, lines 6-7 do recite mixing an antibody but lines 6-7 also recite the antibody being fixed to the medical substance so there can be no mixture. There are no antibodies in solution with the sample. Appellants also state that "...when mixing the antibody with the sample, some of the antibody is coupled with said medical substance contained in the sample in a specific manner...". This statement is not correct since the claim requires the medical substance be fixed to the resonance material in lines 4-5 and thus cannot be in solution with the sample. While Appellants argue that lines 8-9 are not redundant, this appears to be the case since the sample already appears to have contacted the resonance material in lines 6-7.

With respect to lines 11-12, any change in the incident light or reflected light is measured by changes at the surface of the resonance material. Changes in the surface plasmon resonance signal generated by the resonance material are caused by binding of analyte (or a reagent) to the surface of the resonance material (see any of the cited prior art references). Lines 11-12 of claim 24 do not set forth this relationship between the resonance material and analyte. Lines 13-14 go on to say "recognizing an amount of medical substance contained in the sample on the basis of said change of the incident light or the reflected light" which suggests binding reactions in the bulk solution instead of on the surface of the resonance material. However, this is not consistent

with the rest of the claim since lines 4-5 require the medical substance be fixed to the resonance material. In view of this ambiguity it is not clear that binding reactions on the surface of the resonance material are being detected as set forth in the above rejection.

Claim Rejections - 35 U.S.C. § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 14, 15, 17, 19, 22, 24, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Batchelder et al.

Batchelder et al (U.S. Patent 4,844,613) disclose an optical sensor that uses surface plasmon resonance to detect the presence of a specific material. The sensor comprises a prism (11), a transparent body (12), which is coated with a thin gold film (14), and a layer of antibody on the thin film of gold. A photodiode array (16) is provided to detect a signal from the sensor.

Additionally, as shown in Figure 1, the light from source (15) is incident on the prism in the form of a divergent beam. This beam, after refraction at the glass/metal interface passes back through the prism to a detector array (16). The image seen by the array comprises a substantially uniformly illuminated area with a dark band corresponding to the angle or angles at which plasmon resonance reduces the intensity of reflected light. The position of the absorption band may be determined by a microprocessor coupled to the detection array (16) (col. 2, lines 34-44).

In response to this rejection, Appellants argue that in contrast to Batchelder et al, in the claimed invention, it is not an antibody but antigen fixed to a surface of a metal film. The reference does not disclose, teach or otherwise suggest a measuring apparatus or sensor where an antigen to be measured is fixed to a surface of a metal film or resonance material as recited in instant claims 14, 22, and 24. Appellants also argue that according to the present invention, a medical substance having an extremely small molecular weight, which is difficult to detect by conventional technique, can be easily detected and is thus clearly non-obvious over the prior art.

Appellant's arguments have been considered but are not convincing. As set forth above, the function and nature of the antigen recited in the claims is not clearly defined. The antigen can be considered a reagent since it is fixed to the resonance material or it can be considered an analyte since the claims appear to define the "medical substance", which is to be detected, as the antigen. **For the purposes of art rejections, the Examiner viewed the antigen as being an analyte.** The prior art rejections were made with this interpretation in mind. The open "comprising" language of the claims do not exclude the use of antibodies on the surface of the resonance material for detection of antigen by what Appellants call "conventional detecting technology". Batchelder et al (herein referred to as Batchelder) has antibodies immobilized on the surface of the gold film (i.e. resonance material). Analyte antigen becomes fixed to the resonance material once they bind to the antibodies on the surface of the resonance material. The apparatus of Batchelder anticipates the claimed apparatus. The claims do not reflect the apparatus

characterized in Appellant's arguments. The claims do not clearly recite an antigen fixed to the resonance material.

With respect to the detection of medical substances having extremely small molecular weights being "non-obvious over the prior art", it should be noted that the instant claims fail to recite any limitations directed to the detection of medical substances having extremely small molecular weights. Thus, any arguments directed to the detection of such medical substances cannot be relied upon to overcome Batchelder. Also, Batchelder was applied as a 102 reference so any arguments directed to obviousness are improper. Furthermore, Appellants have not provided any evidence to support their assertion that detection of medical substances having extremely small molecular weights cannot be done in the apparatus of Batchelder using what Appellants call "conventional technology".

4. Claims 14, 15, 17, 19, 22, 24, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlan et al.

Finlan et al (U.S. Patent 4,997,278) disclose a sensor that uses surface plasmon resonance to monitor the reaction between a sample and an antibody layer on the sensor. The antibody layer is on a metallic film that is formed on the surface of an optically transmissive component in the form of a hemicylindrical lens and slide.

Additionally, Finlan et al teaches monitoring changes in the angle of incidence of light from the source to monitor changes in resonance caused by the presence of analyte (col. 1, lines 51-68, and col. 2, lines 1-10).

Appellant's arguments traversing this rejection are essentially the same as those set forth above with respect to Batchelder so they have been addressed by the Examiner above.

5. Claims 14, 15, 17, 19, 22, 24, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlan et al.

Finlan et al (U.S. Patent 5,047,213) disclose a biological sensor which utilizes the phenomenon of surface plasmon resonance to detect the refractive index change that occurs when two component, such as antigen and antibody, react with one another. Surface plasmon resonance takes place at the sloping exit surface of an optical waveguide (23). The input end (12) of the optical waveguide is connected to a light source. A layer (25) of metal is applied to the sloping exit surface to cause total internal reflection of the light proceeding down the optical waveguide. Reflected light is detected by detector (13). A sensitive layer of antibody (26) is applied to the metal layer. Sample reacts with the layer of antibody in such a way that the refractive index changes. Provided conditions are correct, this variation in refractive index can be monitored in detector (13) by virtue of the surface plasmon resonance which occurs in the area of total internal reflection (Cols. 1-3).

Appellant's arguments traversing this rejection are essentially the same as those set forth above with respect to Batchelder so they have been addressed by the Examiner above.

6. Claims 14, 16, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart.

Stewart (U.S. Patent 5,229,833) discloses an optical sensor for performing immunoassays. The sensor includes a resonant mirror device (1) and a prism (2) disposed adjacent to each other for coupling a beam of light into the mirror device (1). The mirror device (1) and prism (2) are mounted on a rotatable platform. A beam of light is produced by a He-Ne laser (3) and is linearly polarized with equal TE and TM components by a polarizer (4) arranged at 45 degrees to TE and TM axis. A lens (6) is arranged in the path of the linearly polarized beam of light for focussing the beam of light onto the mirror device (1) thereby providing simultaneously a range of angles of incidence at which the beam of light can be coupled into the mirror device (1) (see Figure 1). When the mirror device is illuminated with a collimated beam from the laser, a resonance will occur at one particular wavelength. This wavelength can be monitored for testing a sample (col. 4, lines 34-56). A layer of antibodies are provided for detection of analyte (col. 4, lines 34-46).

Appellant's arguments traversing this rejection are essentially the same as those set forth above with respect to Batchelder so they have been addressed by the Examiner above.

(11) Response to Argument

Appellant's arguments have been addressed above following each ground of rejection.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Christopher L. Chin
Primary Examiner
Art Unit 1641

Long Le
Supervisory Patent Examiner
Art Unit 1641
(Conferee)

James Housel
Supervisory Patent Examiner
Art Unit 1648
(Conferee)

cchin/cc
April 9, 2001

Rosenman & Colin LLP
575 Madison Avenue
New York, NY 10022-2585